K061943

Section 5: 510(k) Summary

MAY 25 2007

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the Anatomica Cervical System is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices

Sponsor/Manufacturer:	Anatomica AB Stora Åvägen 25 436 34 Askim Sweden Tel: +46 (0)31-748 89 00 Fax: +46 (0)31-28 72 76
Official Correspondent:	Marcos Velez-Duran M Squared Associates, Inc. 719 A Street, NE Washington, DC 20002 Telephone: 202-546-1262 Ext 206 Facsimile: 202-546-3848 Email: MVelez-Duran@MSquaredAssociates.com
Date:	July 7, 2006
Proprietary Name:	Anatomica Posterior Cervical Fixation System
Common Name:	Spinal fixation system
CFR Section Number:	888.3050 Spinal interlaminal fixation orthosis, and 888.3070 Pedicle screw spinal system
Proposed Regulatory Class:	II
Device Product Code:	KWP – Spinal interlaminal fixation orthosis, and MNI – Orthosis, spinal pedicle fixation
Reason for 510(k):	The subject device is a new device intended for commercial distribution in the U.S.A.

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Predicate Devices: Altius OCT System by Interpore Cross, 510(k) K033961 and K043229.

Device Description : The Anatomica Cervical System is a titanium spinal fixation system for occipito-cervico-thoracic (OCT) fixation that contains screws, hooks, and wires that are assembled to rods using one of several types of connectors (expansion loop, compression loop, ME connector, lateral connector, cable lock connector). The occiput screws are for use in the occiput. The wires are for use in the cervical spine. The screws are for use in the thoracic spine (T1-T3). The hooks are for use in the cervical spine.

Intended Use: Both the subject device and the predicate device are intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput to T3).

Performance Testing: Articles provided from regular production lots were tested for Static Bend, Fatigue Bend- fatigue life, Fatigue Bend-incremental load block, and Torsion in accordance with ASTM F1717-01, Standard test methods for spinal implant constructs in a vertebrectomy model.

Basis for Substantial Equivalence: The subject Anatomica Posterior Cervical Fixation System is substantially equivalent to the legally marketed Altius OCT System (Interpore Cross, 510(k) #K033961 and #K043229). Both the predicate and subject device systems are manufactured from Titanium and address the same indications for use. Both systems share similar design features and have been shown through mechanical testing to have similar performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2007

Anatomica AB
% M Squared Associates, Inc.
Mr. Marcos Velez-Duran
Consultant for Anatomica AB
719 A Street, NE
Washington, DC 20002

Re: K061943
Trade/Device Name: Anatomica Posterior Cervical Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: KWP, MNI
Dated: March, 30, 2007
Received: April 2, 2007

Dear Mr. Velez-Duran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

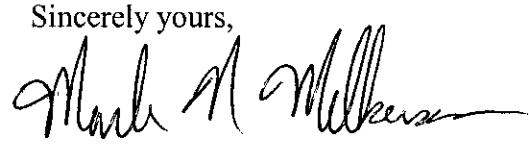
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number: To be assigned

Device Name: Anatomica Posterior Cervical Fixation System

Indication for Use: The Anatomica Posterior Cervical Fixation System is intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput – T3). The system is intended for posterior, cervical, non-pedicle fixation, or for posterior, noncervical pedicle fixation for the following indications:

- degenerative disc disease(DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- spondylolisthesis;
- trauma (i.e., fracture or dislocation);
- spinal stenosis; curvatures (i.e.,scoliosis, kyphosis, and/or lordosis);
- tumor;
- pseudoarthrosis; and
- failed previous fusion.

Occipital bone screws are limited to occipital fixation only. Pedicle bone screws are limited to placement in the upper thoracic spine (T1, T3) when treating thoracic conditions only. Pedicle screws are not intended to be placed in the cervical spine. Hooks and wires (not pedicle screws) are used to achieve cervical fusion for the occipital/cervical loop.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K061943

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